



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Bastian Nuyen et al. Art Unit : Unknown
Serial No. : 09/622,433 Examiner : Unknown
Filed : May 10, 2002
Title : PHARMACEUTICAL FORMULATION OF A DIDEMNIN COMPOUND

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

This paper is responsive to a second Restriction Requirement ("RR2") having a mail date of November 2, 2004. This response is being filed concurrently with a Preliminary Amendment.

Background

Applicants received a first Restriction Requirement ("RR1") having a mail date of July 14, 2004. In RR1, the Office restricted claims 1-11 into the following two groups: Group I, claims 1-8, drawn to a pharmaceutical composition; and Group II, claims 9-11, drawn to methods of preparing a pharmaceutical composition.

Applicants elected Group I without traverse in a response filed on August 5, 2004.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Signature

Denise A Rose

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Denise A Rose

As mentioned above, the subject matter of Group I concerns pharmaceutical compositions. These pharmaceutical compositions have a lyophilized didemninn preparation and reconstitution solution. See, e.g., claim 1 as originally filed, which is reproduced below:

A pharmaceutical composition of a didemninn compound, comprising firstly a lyophilized didemninn preparation including water-soluble material and secondly a reconstitution solution of mixed solvents.

RR2

In RR2, the Office stated that the elected claims were “directed to more than one species of the generic invention” and “[t]hese species are deemed to lack unity of invention because they are not so linked to form a single general inventive concept” (RR2, page 2). Specifically, the Office required that Applicants elect one of the following:

A) Claim 1, a pharmaceutical composition of a didemninn compound, comprising firstly a lyophilized didemninn preparation including water-soluble material (claim 1 is further defined in claim 8 as a vial of lyophilized didemninn preparation including a water-soluble bulking agent).

B) Claim 1, a pharmaceutical composition of a didemninn compound, comprising secondly a reconstitution solution of mixed solvents (claim 1 is further defined in claim 8 as a separate vial of a premix of non-ionic surfactant/ethanol/water) (RR2, page 3).

The Office further stated:

Since Applicant claims that the pharmaceutical composition comprises of two different vials containing the different active ingredients, the pharmaceutical composition reads more on a Kit instead of a pharmaceutical composition.
Applicant may choose to replace the term ‘pharmaceutical composition’ with the term ‘Kit’ to appropriately define its invention (RR2, page 3, emphasis added).

In a telephone conference with Examiner Winston on March 10, 2005, Applicants were informed that the claims would be examined in their entirety if amended to replace the terms “pharmaceutical composition” and “composition” in the preambles of claim 1 and claims 2-8,

respectively with the term "kit." It is Applicants' understanding that an election of A or B above would only be necessary if Applicants retained the terms "pharmaceutical composition" and "composition" in claims 1-8.

Applicants' Response

Responsive to RR2, Applicants submit the amendments to claims 1-8, which are set forth in the accompanying Preliminary Amendment. As suggested by the Examiner, claims 1-8 have been amended to replace the terms "pharmaceutical composition" in the preamble of claim 1 and the term "composition" in the preamble of claims 2-8 with the term "kit." Applicants submit that the foregoing is *bona fide* attempt to provide the Office with a fully responsive and compliant reply to the presently outstanding action.

In the event that an election is nonetheless required, Applicants elect Group A, a pharmaceutical composition of a didemnin compound, comprising firstly a lyophilized didemninn preparation including water-soluble material, which is readable on new claims 12-25 set forth.

Applicants encourage the Examiner to contact their undersigned representative to discuss the restriction groups or this election. Applicants thank the Examiner in advance for this courtesy.

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Attorney's Docket No.: 14620-012US1 / JC/USP78531

Applicants respectfully request that claims 1-25 be examined and allowed.

Enclosed is a \$1,590 check for the Four-Month Petition for Extension of Time fee.
Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney
Docket No.: 14620-012US1.

Respectfully submitted,

Date: _____

1 Apr 05

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